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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/724,676 | 11/28/2000 | Zurit Levine | ILEX:032 | 9311 |

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| EXAMINER | |
|---|---|
| MARSCHEL, ARDIN H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | 8 |

DATE MAILED: 07/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/724,676 | LEVINE ET AL. | |
| | Examiner | Art Unit | |
| | Ardin Marschel | 1631 | |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-73* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR ' 1.821(a)(1) and (a)(2). See, for example, SEQ ID Nos. in the claims. However, this application fails to comply with the requirements of 37 CFR ' 1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, statements under 37 CFR ' 1.821(f) and (g), and SEQ ID Nos cited along with each sequence in the specification or Figures. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4, 8-11, and 16-58; drawn to isolated nucleic acid sequences, and vectors and cells containing them, classified in class 536, subclass 23.1. If this Group is elected then the below summarized sequence election is also required.

II. Claim 3, drawn to an amino acid sequence, classified in class 530, subclass 300. If this Group is elected then the below summarized sequence election is also required.

III. Claims 5-7, drawn to antibodies, classified in class 530, subclass 387.1. If this Group is elected then the below summarized sequence election is also required.

IV. Claims 12-15, drawn to pharmaceutical compositions selected from amino acid sequences, antibodies, and nucleic acid sequences, classified in class 530, 530, and 536, subclasses 300, 387.1, and 23.1; respectively. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

V. Claims 59, 63, and 64; drawn to methods for detecting of a variant nucleic acid sequence, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.

VI. Claim 60, drawn to methods of determining the level of a variant nucleic acid sequence, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.

VII. Claims 61 and 62, drawn to methods of determining a ratio between a variant level and its original sequence level, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.

VIII. Claim 65, drawn to detecting a variant amino acid sequence, classified in class 435, subclass 7.1. If this Group is elected then the below summarized sequence election is also required.

IX. Claim 66, drawn to methods for detecting the level of an amino acid sequence, classified in class 435, subclass 7.1. If this Group is elected then the below summarized sequence election is also required.

X. Claims 67 and 68, drawn to methods for determining the ratio between variant amino acid sequence level and its original sequence level, classified in class 435, subclass 7.1. If this Group is elected then the below summarized sequence election is also required.

XI. Claims 69-73, drawn to data directed to nucleic acid sequences, classified in class 703, subclass 11. If this Group is elected then the below summarized sequence election is also required.

**Sequence Election Requirement Applicable to All Groups:**

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus

deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

**SPECIE ELECTION REQUIREMENT FOR GROUP IV ONLY:**

This application contains claims directed to the following patentably distinct species of the claimed invention:

IV-A: nucleic acid pharmaceutical compositions

IV-B: amino acid pharmaceutical compositions

IV-C: antibody pharmaceutical compositions

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 12-15 are generic to the above species. The species of composition are distinct for the same reasons as given below for these types of chemical structures.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups [I, IV(nucleic acid compositions), and V-VII); Groups [II, IV(amino acid compositions), and VIII-X); Groups [III and IV(antibody compositions)]; and XI are independent inventions because they are directed to different chemical types or invention types regarding the critical limitations therein. For Groups II etc. the critical feature is an amino acid sequence; for Groups I etc. the critical feature is nucleic acid; for Group III etc. the critical feature is an antibody, and for Group XI the critical feature is data for nucleic acid sequences. It is acknowledged that various processing steps may cause a polypeptide of Groups II etc. to be directed as to its synthesis by a polynucleotide of Groups I etc., however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, antibody, and data Groups supports the undue search burden if both were examined together. Additionally, polynucleotides,

polypeptides, antibodies, and data have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I etc.), (II etc.); (III etc.); and (XI) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I, IV(nucleic acid compositions), and Groups V-VII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. ' 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Groups V-VII as well as for pharmaceutical usage. One use is directed to nucleic acid detection and the other for therapy. Alternatively, the nucleic acids of Group I can be used in antisense therapy which is also a clearly distinct usage of such nucleic acids. It is additionally noted that Groups V-VII are distinct as they are directed to distinct results of detection as follows which are generally not published together: Group V:presence or absence detection; Group VI: quantitation; and Group VII: ratio detection generally associated with genetic profiling.

The inventions of Group II, IV(amino acid compositions) and Groups VIII-X are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. ' 806.05(h)). In the instant case the polypeptides of Group II can be used in the distinct processes of the inventions of Groups VIII-X and in therapeutic processes to replace a missing protein, or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing. Similarly, the Group IV amino acid compositions may be utilized for detection purposes or screening assays for potential therapeutic activity. It is additionally noted that Groups VIII-X are distinct as they are directed to distinct results of detection as follows which are generally not published together: Group VIII:presence or absence detection; Group IX: quantitation; and Group X: ratio detection generally associated with genetic profiling.

The inventions of Group III and IV(antibody compositions) are related as products with distinct processes of use and thus a distinct search burden would be present if they were searched together. The Group III antibodies may alternatively be utilized in immunoassays as well as for antibody affinity columns for purification of recognized antigen.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR ' 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. ' 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. ' 1.48(b) and by the fee required under 37 C.F.R. ' 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 26, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER